



## Office of Pesticide Programs

### Label Review Manual Chapter 8: Precautionary Labeling

#### Introduction

Precautionary labeling provides the pesticide user with information regarding the potential toxicity, irritation and sensitization hazard associated with the use of a pesticide. The precautionary labeling also identifies the precautions necessary to avoid exposure, any personal protective equipment (PPE) which should be used when handling a pesticide and first aid in case of accidental exposure.

This chapter is organized into the following five major parts:

- Background Information
- Determination of Products Subject to the Worker Protection Standard
- Precautionary Labeling
- First Aid (Statements of Practical Treatment)
- Optional Labeling and Deviations

#### Background Information

1. **ACUTE TOXICITY DATA:** The precautionary labeling which includes the signal word, personal protective equipment and first aid statements is normally determined by six acute toxicity studies and product composition. The acute oral, acute dermal and acute inhalation studies measure the lethality of a product via the designated route of exposure. The primary eye irritation and primary skin irritation studies measure the severity of irritation or corrosivity caused by a product. The dermal sensitization study determines whether a product is capable of causing an allergic reaction. With the exception of the dermal sensitization study each acute toxicity study is assigned a toxicity category (See Table 1 below).

**Table 1 - Toxicity Categories**

Study	Category I	Category II	Category III	Category IV
Acute Oral	Up to and including 50 mg/kg	> 50 thru 500 mg/kg	> 500 thru 5000 mg/kg	> 5000 mg/kg
Acute Dermal	Up to and including 200 mg/kg	> 200 thru 2000 mg/kg	> 2000 thru 5000 mg/kg	> 5000 mg/kg
Acute Inhalation <sup>1</sup>	Up to and including 0.05 mg/liter	> 0.05 thru 0.5 mg/liter	> 0.5 thru 2 mg/liter	> 2 mg/liter
Eye Irritation	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days	Corneal involvement or irritation clearing in 8-21 days	Corneal involvement or irritation clearing in 7 days or less	Minimal effects clearing in less than 24 hours
Skin Irritation	Corrosive (tissue destruction into the dermis and/or scarring)	Severe irritation at 72 hours (severe erythema or edema)	Moderate irritation at 72 hours (moderate erythema)	Mild or slight irritation (no irritation or slight erythema)

<sup>1)</sup> 4 hr exposure

2. **GUIDANCE DOCUMENTS USED TO DETERMINE LABELING:** The Code of Federal Regulations specifies both acute toxicity categories (40 CFR 156.10(h)(1)(i)) and precautionary labeling statements associated with each toxicity category (40 CFR 156.10(h)(2)). These acute toxicity categories and precautionary labeling statements are not currently being used by the Agency as they are less detailed and provide less protection for pesticide users than other guidance. The 40 CFR 156.10(h)(2)(i) states that precautionary labeling statements listed therein can be modified or expanded to reflect specific hazards. The precautionary labeling provided in the Federal Register notice issued on 9/26/84 entitled Proposed Rule on Labeling Requirements (Volume 49, Number 188) is being used because it is more detailed and provides better protection. The acute toxicity categories listed in the proposed rule are also being used with one exception. The acute inhalation toxicity categories currently used are from a 2/1/94 Health Effects Division paper entitled "Interim Policy for Particle Size and Limit Concentration Issues in Inhalation Toxicity Studies. The Worker Protection Standard issued in 1992 is the major guidance document for labeling of agricultural products. That document is also being used to determine type of respiratory protective equipment for products which are not subject to the WPS.

### **Determination of Products Subject to the Worker Protection Standard (WPS)**

Review this section to determine whether the label under review involves a product, which is subject to the WPS. WPS does not apply to manufacturing use products, or to unregistered pesticides used under an experimental use permit issued under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 5 or under an exemption issued under FIFRA section 18. This determination is important when reviewing the following sections of this manual because the personal protective equipment for WPS products is more specific and there are some additional labeling requirements.

- Does the product bear directions for use involving the production of an agricultural plant on a farm, forest, nursery, or greenhouse or does the product bear labeling which could reasonably permit such a use?
  - **NO:** The product is not subject to the WPS. Go to the next section on Precautionary Labeling.
  - **YES:** Does the product meet any of the exceptions listed below?

**EXCEPTIONS:** Does the product bear directions solely for any of the following uses?

- For mosquito abatement, Mediterranean fruit fly eradication, or similar wide-area public pest control programs sponsored by governmental entities.
- On livestock or other animals, or in or about animal premises.
- On plants grown for other than commercial or research purposes, which may include plants in habitations, home fruit and vegetable gardens, and home greenhouses.
- On plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for aesthetic purposes or climatic modification.
- In a manner not directly related to the production of agricultural plants, including, but not limited to, structural pest control, control of vegetation along rights-of-way and in other non-crop areas, and pasture and rangeland use.
- For control of vertebrate pests.

- As attractants or repellents in traps.
- For research uses of unregistered pesticides.
- **NO:** The product IS subject to the WPS.
- **YES:** The product is NOT subject to the WPS.

Please Remember:

In some cases it is not clear whether or not a product is "in-scope" of the WPS. If the intention is to remove the product from the scope of the WPS, language should be used that limits where this product can be applied, rather than who may apply it. This can be done by adding one of the following exclusionary statements. For example:

"Not for use on turf being grown for sale or other commercial use as sod, or for commercial seed production, or for research purposes."

or

"For use only on home lawns."

For further details, see PR Notice 93-11, Supplement F.

Label Reviewer: Be aware, that PR Notice 93-11, Supplement G provides guidance on splitting the product label to allow the non-agricultural uses to be labeled separately and avoid WPS requirements.

### Precautionary Labeling

If toxicity categories are known: Use the toxicity categories to determine the appropriate labeling identified in the following sections of this chapter.

If toxicity categories are not known, as in the case of many me-too submissions, the label review will essentially involve a comparison of the draft label against the cited label. **Cited labels often contain errors themselves. To ensure that these errors are not passed on to the Me-too label, review the following sections of this chapter to verify that the draft and cited labels are correct.**

1.SIGNAL WORD: Review the following to determine the correct signal word and its location:

- A. Correct Signal Word: The signal word is determined by the most severe toxicity category assigned to the five acute toxicity studies or by the presence of special inerts (methanol in concentrations of 4% or more). Refer to the acute toxicity data review to determine the most severe toxicity category. Also check the confidential statement of formula to determine if methanol is present. If acute toxicity categories are not known, the signal word on the label under review must be identical to the signal word on the cited product. Signal words are as follows:

Toxicity Category I - DANGER

Toxicity Category II - WARNING

Toxicity Categories III & IV - CAUTION

- B. **Required Location:** The signal word may only appear in three places on the label. It must appear on the front panel of the label immediately below the child hazard warning statement, in the precautionary labeling section immediately below the subheading "Hazards to Humans and Domestic Animals" and in the WPS posting statement if one is on the label.
- C. **Other Requirements:** Make sure that the label text does not contain the terms "caution," "warning" or "danger" except as the signal word for that label. (e.g., "CAUTION: Wash hands before eating, or smoking" on a "WARNING" label). Another example is the statement required by California's Proposition 65 which normally requires the term "warning." Registrants should use the term "notice" or "attention" instead so that it does not conflict with the EPA required signal word. Make sure that the signal word does not appear on the same line with the child hazard warning and that the signal word runs parallel with other label text. It is preferred that the signal word appears in all capital letters.
- D. **WPS Products:** Products subject to the WPS which are classified as toxicity category I or II must also bear the corresponding Spanish signal word and the Spanish statement provided below. The Spanish signal word and the statement below must appear in close proximity to the English signal word. The Spanish signal word for toxicity category I is "PELIGRO" and the Spanish signal word for toxicity category II is "AVISO." The statement which must appear on toxicity category I and II WPS products is as follows:

**"Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)"**

2. **POISON - SKULL & CROSSBONES DETERMINATION:** The word "POISON" and the skull and crossbones symbol are required whenever a product is classified as toxicity category I due to the results of either the acute oral, acute dermal, or acute inhalation toxicity studies (40 CFR 156.10(h)(1)(i)) or if the inert (Methanol 4% or more) are present in the product [1984 proposed labeling rule, Part 156.50].
- A. **Required Location:** The word "Poison" and the skull and crossbones symbol must appear in immediate proximity to the signal word which must be "DANGER."
- B. **Display Requirements:** "Poison" must appear in red on a contrasting background. If the proposed label does not indicate these display requirements, include this requirement in your response to the registrant.

**Table 2 - Acute Toxicity Category Determination for Sample Products**

Type of Study	Product A	Product B	Product C	Product D	Product E
Acute Oral	III	IV	I	III	II
Acute Dermal	IV	III	III	IV	II
Acute Inhalation	III	IV	III	III	II
Primary Eye	III	II	I	I	II
Primary Skin	IV	IV II	IV	II	
Special Inert	No	No	No	No	Yes
Correct Signal Word	CAUTION	WARNING	DANGER*	DANGER	DANGER*

\*Product C and Product E must also bear additional labeling (Skull & Crossbones symbol in close proximity to the word "POISON" which must appear in red on a contrasting background). Product C must bear the additional labeling as a result of the toxicity category I classification for the acute oral toxicity study. Product E must bear

the additional labeling because it contains a special inert (Methanol) which is described above in the first paragraph.

3. **CHILD HAZARD WARNING STATEMENT:** The phrase "Keep Out Of Reach Of Children" is required on almost all product labels. The child hazard warning statement may be completely omitted for manufacturing use products. A modified child hazard warning statement may be used for products where child contact is expected. For products requiring a modified statement, make sure that the statement is appropriate for the use pattern. Examples of appropriate statements are as follows: "Do not allow children to apply product" or "Do not allow children to play with pet collar" (1984 proposed labeling rule, 156.46).
  - A. **Required Location:** The child hazard warning statement must appear on the front panel (40 CFR 156.10(h)(1)(ii)).
  - B. **Other Requirements:** It is also preferred that the child hazard warning appears on a separate line above the signal word. The CFR does not include this specific requirement. However, it is included in the 1984 proposed labeling rule. When the signal word and child hazard warning appear on the same line, a pesticide user may assume that the signal word is intended more so for children rather than as a general precaution for all persons. If the label under review has the signal word and child hazard warning on the same line, instruct the registrant to revise the label. Also make sure that the child hazard warning statement runs parallel with other label text.

Make sure that the "Precautionary Statements" and the "Directions for Use" do not contain any statements which imply that the product may be used by children. For example, draft labels of products intended to repel insects may contain instructions such as "Do not allow use by small children without close adult supervision." Such labeling is unacceptable as it implies that a child can apply the product as long as an adult watches. Such a statement conflicts with the child hazard warning statement. Pesticide products should not be applied by children because they may be incapable of reading and correctly following the directions for use.

4. **PRECAUTIONARY STATEMENTS:** Precautionary statements are required for each acute toxicity study classified as toxicity category I, II, or III and for products found to be dermal sensitizers.
  - A. **Required Header:** The precautionary statements must appear under the heading "Precautionary Statements" and the appropriate subheading "Hazard to Humans and Domestic Animals." The phrase ". . . and Domestic Animals" may be left off if it is inappropriate or list separately from Hazard to Humans. The signal word must appear after the subheading.
  - B. **Required Location:** The precautionary statement section may appear on any panel. Please note that the precautionary statements must not be included within the "Directions For Use" section. With the exception of PPE for early reentry, all PPE must be located in the precautionary labeling section. **Order of Statements:** The precautionary statements should be organized so that the most severe routes of exposure as demonstrated by the toxicity category classification are listed first.
  - C. **Fumigants:** Refer to PR Notice 84-5 (Reference: PR-84-05) and Registration Standards and/or Reregistration Eligibility Documents (REDs) for precautionary statements.
  - D. **Determining Statements For All Other Products:** Select precautionary statements from the tables below based on the toxicity category assigned to each study. In cases where the toxicity categories are not known, the precautionary labeling for at least one route of exposure must be consistent with the signal word. Sentences from the various tables may be combined to form a

concise paragraph containing the precautionary labeling statements. Repetitious sentences should be omitted.

(1) Products Not In Scope of WPS: Use the precautionary statements and PPE contained in this section, Tables 3 through 8 and then go to the section entitled First Aid (Statements of Practical Treatment).

(2) Products In Scope of WPS: Use the precautionary statements in this section, Tables 3 through 8. Disregard the PPE contained in the Tables 3 through 8. Refer to Sections 5 through 8 to determine the PPE for WPS products.

**Table 3 - Acute Oral Toxicity Study\***

Toxicity Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER  Skull & Crossbones required	Fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.
II	WARNING	May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.
III	CAUTION	Harmful if swallowed. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

\*Products Containing 4% or more of Methanol: Add the following to the precautionary statements: "Methanol may cause blindness."

**Table 4 - Acute Dermal Toxicity Study**

Toxicity Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER  Skull & Crossbones required	Fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective clothing and gloves (specify protective clothing and type of gloves). Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.
II	WARNING	May be fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective clothing and gloves (specify protective clothing and type of gloves). Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

**Table 5 - Acute Inhalation Toxicity Study**

Toxicity Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER Skull & Crossbones required	Fatal if inhaled. Do not breathe (dust, vapor, or spray mist).* [Identify specific respiratory protective device approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.]** Remove contaminated clothing and wash clothing before reuse.
II	WARNING	May be fatal if inhaled. Do not breathe (dust, vapor or spray mist).* Wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Harmful if inhaled. Avoid breathing (dust, vapor or spray mist).* Remove contaminated clothing and wash clothing before reuse.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

\* Choose the word which appropriately describes the product during use. \*\*Refer to Section to determine the specific respiratory protective device. This section can be used for both WPS and Non-WPS products.

**Table 6 - Primary Eye Irritation Study**

Toxicity Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER	Corrosive.* Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses).** Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
II	WARNING	Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses).** Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

\*The term "corrosive" is not required if only eye irritation (redness) was observed during the study and was still present at day 21.

\*\*Use the term "safety glasses" in the precautionary labeling for residential use products.

**Table 7 - Primary Skin Irritation Study**

Toxicity Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER	Corrosive. Causes skin burns. Do not get in eyes or on clothing. Wear protective clothing and gloves (specify protective clothing and type of gloves)*. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
II	WARNING	Causes skin irritation. Do not get on skin or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

\*The need for rubber (homeowner products) or chemical resistant gloves must be determined on an individual basis. Some products cause blistering if confined under clothing.

**Table 8 - Dermal Sensitization Study**

Study Results	Precautionary Statement
Product is a sensitizer or is positive for sensitization.	Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
Product is not a sensitive or is negative for sensitization.	No labeling is required for this hazard.

5. WPS PERSONAL PROTECTIVE EQUIPMENT (PPE) REQUIREMENTS: Personal protective equipment is required for both pesticide handlers as well as workers who reenter treated areas prior to the expiration of the restricted entry interval (REI).
- A. Determining Toxicity Categories for Each Route of Exposure: If all acute toxicity categories are known, skip to Section B. If any acute toxicity categories are unknown, review this section to determine the preferred order for selecting alternate data to establish a toxicity category for the missing data:
- (1) If available, use the toxicity categories assigned to the acute dermal toxicity, acute inhalation toxicity, primary eye irritation, and primary skin irritation data on the end-use product.
  - (2) If either the acute dermal toxicity or acute inhalation toxicity data are missing, use the toxicity category assigned to the acute oral toxicity data.
  - (3) If the acute oral, acute dermal and acute inhalation toxicity data are missing, use the product signal word to determine the equivalent toxicity category.
- B. WPS Products: Use the toxicity categories to determine from Table 9 whether the label under review contains the appropriate PPE.

#### Statements for Contaminated Personal Protective Equipment

Use the following statement if the signal word is "Danger" or "Warning" and the product is a concentrate (diluted before use, or is an ultra-low-volume or low volume concentrate, or contains more than 50% active ingredient):

"Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

**Table 9 - Personal Protective Equipment for WPS Products**

Route of Exposure	Toxicity Category by Route of Exposure of End-Use Product <sup>1</sup>			
	I (DANGER)	II (WARNING)	III (CAUTION)	IV (CAUTION)
Dermal Toxicity or Skin Irritation Potential <sup>1</sup>	Coveralls worn over long-sleeved shirt and long pants	Coveralls worn over short-sleeved shirt and short pant	Long-sleeved shirt and long pants	Long-sleeved shirt and long pant
	Socks	Socks	Socks	Socks
	Chemical-resistant footwear	Chemical-resistant footwear	Shoes	Shoes
	Gloves <sup>3</sup>	Gloves <sup>3</sup>	Gloves <sup>3</sup>	No minimum <sup>5</sup>



	Toxicity Category by Route of Exposure of End-Use Product <sup>1</sup>			
Inhalation Toxicity	Respiratory protection device <sup>4</sup>	Respiratory protection device <sup>4</sup>	No minimum <sup>5</sup>	No minimum <sup>5</sup>
Eye Irritation Potential	Protective eyewear	Protective eyewear	No minimum <sup>5</sup>	No minimum <sup>5</sup>

<sup>1</sup>Refer to section 6 for PPE for product using Water Soluble Packaging.

<sup>2</sup>If dermal toxicity and skin irritation toxicity categories are different, PPE shall be determined by the more severe toxicity category of the two. If dermal toxicity or skin irritation is category I or II, refer to Section C below to determine if additional PPE is required beyond that specified in Table 9.

<sup>3</sup>Refer to Section 7 to determine the specific type of chemical-resistant glove.

<sup>4</sup>Refer to Section 8 to determine the specific type of respiratory protection.

<sup>5</sup>Although no minimum PPE is required for these toxicity categories and routes of exposure, the Agency may require PPE on a product-specific basis.

- C. PPE for Dermal Protection: Additional PPE is required for products which are classified as toxicity category I or II for acute dermal toxicity or skin irritation. If the label under review does not involve a category I or II classification for either of these studies, skip this section and go to Section 6. If the label under review does involve a category I or II classification for either the acute dermal toxicity or skin irritation, review the following table to determine the additional PPE which must appear on the label under review.

**Table 10 - Additional Dermal toxicity and/or Skin Irritation PPE**

Conditions Requiring Additional PPE and Labeling	Required PPE and Labeling
All products which are not ready to use and do not require a chemical resistant suit must bear the corresponding statement:	"When mixing and loading wear a chemical resistant apron."
All products having applications which might involve overhead exposure must bear the corresponding statement:	"For overhead exposure wear chemical-resistant headgear."
All products involving use of equipment other than the product container to mix, load or apply the product must bear the corresponding statement:	"When cleaning equipment add a chemical-resistant apron."

6. ENGINEERING CONTROL SYSTEMS SECTION: If the product in the water soluble bag is subject to the Worker Protection Standard, then the following language should be placed in the engineering control section using the placement in PR Notice 93-7.

- A. This label language is to be used for end-use products classified as category I or II for either acute dermal toxicity OR skin irritation potential. (NOTE: If either of these data is not available, use the end-use product signal word as a surrogate. Signal words DANGER and WARNING indicate toxicity category I and II respectively.)

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

"Water-soluble packets when used correctly qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water-soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves."

"IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down."

- B. This label language is to be used for end-use products classified as category III or IV for acute dermal toxicity AND skin irritation potential. (NOTE: if either of these data is not available, use the end-use product signal word as a surrogate. Signal word CAUTION indicates toxicity category III or IV.)

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

"Water-soluble packets when used correctly qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water-soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, and socks."

"IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down."

7. **CHEMICAL RESISTANT GLOVE SELECTION FOR HANDLERS:** Chemical resistant gloves are required for all WPS products classified as toxicity category I, II, or III for acute dermal toxicity or primary skin irritation. Review the types of chemical resistant gloves below, and determine if the label lists the appropriate glove type based on the product formulation. Please note that the registrant can specify another chemical resistant glove type other than those specified below if information is available that indicates that another glove type provides greater protection. If the label bears another chemical resistant glove type and the registrant has indicated that it is more protective based on available information, allow that glove type to remain on the label. If the label bears another chemical resistant glove type than those listed below and the registrant has not indicated that it is more protective based on available information, request that the registrant verify that the appropriate chemical resistant glove type is on the label. The label must indicate the specific type of chemical resistant glove (such as nitrile, butyl, neoprene, and/or barrier laminate). See the solvent list in PR Notice 93-7, pp. 13-15. For those solvents not listed contact the Chemistry and Exposure Branches (CB-I or II). Listed below are the standard glove types required by the WPS.

- A. **Solid Formulations** applied as solids or formulations containing only water as the solvent or solvents other than water less than 5%, the glove statement shall specify "waterproof gloves." (Reference: Supplement III, Main Labeling Guidance, Page 11, of PR Notice 93-7.
- B. **Aqueous-Based Formulations** applied as formulated or diluted solely with water for application, the glove statement shall specify "waterproof gloves."
- C. **Other Liquid Formulations** which are formulated or diluted with liquids other than water (constitutes more than 5% of the end-use product), the glove statement shall specify "chemical-resistant (such as nitrile or butyl) gloves."

**D. Gaseous Formulations or Formulations applied as Gases** will retain any existing glove statement established before 10/20/92 including any glove prohibition statement. If no glove statement or glove prohibition currently exist on the label, then the glove statement shall be "chemical-resistant (nitrile or butyl) gloves."

8. **SPECIFIC RESPIRATORY PROTECTION DEVICE (RPD) SELECTION FOR HANDLERS:** RPD(s) are required for all products classified as toxicity category I or II for acute inhalation. Review the RPD types below and determine if the label lists the appropriate type based on the product description and toxicity category. Please note that if the registrant has submitted information to support the selection of another type of RPD, which is more protective, allow the registrant to retain that RPD requirement on the label under review. Information that could support an alternate RPD could be the submission of the product vapor pressure indicating that the RPD specified in the list below would not provide adequate protection or may pose an increased risk to the user unnecessarily.

**A. Gases Applied Outdoors:** Products that are formulated or applied as a gas (space and soil fumigants) and that may be applied outdoors must bear labeling specifying the following RPD requirements and statement:

"For handling activities outdoors, use either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)."

**B. Gaseous Products Used in Enclosed Areas:** Products that are formulated or applied as a gas (space and soil fumigants) and that may be used in greenhouses or other enclosed areas must bear labeling specifying the following RPD requirements and statement:

"For handling activities in enclosed areas, use either a supplied-air respirator with MSHA/NIOSH approval number prefix TC-19C, or a self-contained breathing apparatus (SCBA) with MSHA/NIOSH approval number TC-13F."

**C. Solid Products:** Products that are formulated and applied as solids must bear labeling specifying the following RPD requirements and statement:

"For handling activities, use a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

**D. Liquid Products in Toxicity Category I:** Products that are formulated and applied as liquids must bear labeling specifying the following RPD requirements and statement:

"For handling activities, use either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G)."

**E. Liquid Products in Toxicity Category II:** Products that are formulated or applied as liquids must bear labeling specifying the following RPD requirements and statement:

"For handling activities during [insert applicable terms based on directions for use: airblast, mistblower, pressure greater than 40 p.s.i. with fine droplets, smoke, mist, fog, aerosol or direct overhead] exposures, wear either a respirator with an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister

approved for pesticides (MSHA/NIOSH approval number prefix 14G). For all other exposures, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

9. **REQUIRED LOCATION FOR PPE LABELING FOR APPLICATORS AND OTHER HANDLERS:** PPE statements for applicators and other handlers must appear in the "PRECAUTIONARY STATEMENTS" section of the labeling. Refer to PR Notice 93-7 Supplement 3-A, Part 1 Product Worksheet. All products subject to the WPS must bear the following statements:

"Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

10. **LABELING AND PPE FOR EARLY REENTRY WORKERS - WPS Products**

- A. All products subject to the WPS must bear the following statements for workers who reenter the treated area prior to the expiration of the reentry interval:

"PPE Required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear: (Insert all PPE required for applicators and other handlers. Omit any respiratory protective devices)."

- B. Additional Early Reentry Worker PPE Requirements: The following modifications must be made to the early reentry worker labeling and PPE required in Section A. above:

- If the handler body clothing requirement is a long-sleeved shirt and long pants, then the early-entry worker requirement shall be "coveralls."
- If there is no handler requirement for or against gloves, then the early-entry requirement shall be "waterproof gloves."

- C. Required Location for Early-Reentry Worker Labeling and PPE Labeling: PPE statements for early-reentry workers must appear in the "DIRECTIONS FOR USE" section of the labeling under the heading "AGRICULTURAL USE REQUIREMENTS" immediately after the restricted-entry statement.

11. **USER SAFETY RECOMMENDATIONS:** If the product falls within the scope of WPS, then a User Safety Recommendations box, as indicated in PR Notice 93-7, Supplement Three, must also appear in a separate box on the label containing appropriate user safety information. The preferred location for this box is at the end of the section headed "Hazards to Humans (and Domestic Animals).

**First Aid (Statement of Practical Treatment)**

A first aid statement is required for each route of exposure (oral, dermal, inhalation, eye and skin) where the toxicity study has been classified as category I, II, or III. It is acceptable for the registrant to include first aid statements (category III statements) for studies that are classified as category IV.

1. **REQUIRED HEADER:** Any of the following headings are acceptable: First Aid, Statement of Practical Treatment or Practical Treatment. The heading "Antidote" cannot be used unless a specific antidote is recommended. The label should bear the heading which is most readily recognized by the intended users of the product. This determination will be made by the registrant.

2. **CONTENT AND CLARITY:** First aid statements must be brief, clear, simple and in straightforward language so that the average person can easily and quickly understand the instructions. First aid statements should be appropriate for all ages or when necessary, should include distinctions between the treatments for different ages, i.e., children vs. adults. The first aid statements should be such that any reasonably competent individual could perform them. First aid statements should not include procedures which must be performed by medical personnel or require specialized equipment (See Note to Physician) section.

If the product contains an organophosphate (i.e., an organophosphorus ester that inhibits cholinesterase) or an N-methyl carbamate (i.e., an N-methyl carbamic acid ester that inhibits cholinesterase), the appropriate term shall be shown in the First Aid statement.

3. **ORDER OF STATEMENTS:** First aid statements should be organized so that the most severe routes of exposure as demonstrated by the toxicity category classification are listed first.
4. **REQUIRED LOCATION:** First aid statements must appear on the front panel of the label for all products classified as toxicity category I for acute oral, acute dermal, or acute inhalation exposure (40 CFR 156.10(h)(1)(i)). First aid statements triggered by any other exposure classification may appear on the front, side or back panel of the product label. However, any time first aid statements appear somewhere other than on the front panel, a referral statement such as "see side/back panel for first aid" must appear on the front panel in close proximity to the signal word. Furthermore, first aid statements on the side or back panel should be grouped near the other precautionary labeling, yet set apart or distinguishable from the other label text.
5. **FIRST AID STATEMENTS FOR FUMIGANTS:** Refer to PR Notice 84-5 (Reference: PR-84-05) and Registration Standards/REDs.
6. **FIRST AID STATEMENTS FOR ALL OTHER PRODUCTS:** Review the following sections to determine the appropriate first aid statements for each route of exposure.
  - A. **Acute Oral:** Use the following flow chart to determine the appropriate oral first aid statements. Please note that oral first aid statements are controversial and there are differing opinions within the medical community concerning whether emesis (vomiting) should be recommended. Until the Agency resolves this issue, in situations where the registrant has recommended an oral first aid statement that differs from those on the flowchart, instruct the registrant to modify the statement according to the flowchart or provide a justification for the use of the alternate statement.

If the registrant's justification indicates that the proposed first aid statement was based on medical staff evaluation of the product, let the registrant retain the proposed first aid statement as long as it meets the requirements set forth in "Content and Clarity of Statements" and does not involve the use of salt water for emesis (PR Notice 80-2 (Reference: PR-80-02)). If the registrant indicates that the statement was selected by simply referring to another product, request that the registrant revise the statement based on the flow chart.

### Determining the Acute Oral Exposure First Aid Statement

Is the active ingredient: zinc phosphide?  IF NO   	IF YES---->	Use the following Statement:  IF SWALLOWED: Immediately call a Poison Control Center or doctor, or transport the patient to the nearest hospital. Do not drink water. Do not administer anything by mouth or make the patient vomit unless advised to do so by a doctor."
Is the product tox category I or II for oral toxicity?  IF NO   	IF YES---->	Use the below for "All other Products."
Is product corrosive (pH < 2 or > 11.5) or is product toxicity category I or II for eye or dermal irritation?  IF NO   	IF YES---->	Use the following statement:  IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person.  Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol."
Does the product contain > 10% petroleum distillates?  IF NO   	IF YES---->	Use the following statement:  IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Avoid alcohol.
All other Products.  NOTE: Products in tox category IV for oral toxicity, do not require a first aid statement. However, if the registrant chooses, he may use either of these statements on his label.	IF YES---->	Use either of the following statements:  IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.  OR  IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available by administering syrup of ipecac. If person is unconscious, do not give anything by mouth and do not induce vomiting.

NOTE: The criteria in this flowchart are listed in priority order, with the highest at the top. If you have a product/chemical that meets more than one criteria, use the criteria that appears first on the chart. Do not use more than one criteria!

- B. Acute Dermal and Primary Skin Irritation: Since both these studies focus on the dermal route of exposure, the first aid statements for these two studies can be combined when required for both studies. If a statement is required for both studies, use the first aid statement required for the acute dermal toxicity study if both studies are in the same acute toxicity or for the more severe acute toxicity category if the studies are in different acute toxicity categories.

**Table 11 - Skin Irritation Statements**

Toxicity Category	Required First Aid Statement
I	IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
II	Same as above
III	IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.
IV	Statement not required. Registrant may use category III statements, if he chooses

**Table 12 - Dermal Toxicity Statements**

First Aid Statement Based on Acute Dermal Toxicity Study	
Toxicity Category	Required First Aid Statement
I	IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
II	Same as above
III	Same as above
IV	Statement not required. Registrant may use category III statements, if he chooses

- C. Acute Inhalation: Selection of the first aid statement is straightforward and is based on the toxicity category assigned to the particular study.

**Table 13 - Acute Inhalation Statements**

Toxicity Category	Required First Aid Statement
I	IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.
II	Same as above
III	Same as above
IV	Statement not required. Registrant may use category III statements, if he chooses

- D. Primary Eye Irritation: Selection of first aid statement is straightforward and is based on the toxicity category assigned to the particular study.

**Table 14 - Eye Irritation Statements**

Toxicity Category	Required First Aid Statement
I	IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.
II	Same as above
III	IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IV	Statement not required. Registrant may use category III statements, if he chooses

## 7. NOTE TO PHYSICIAN

- A. When Required: The "Note to Physician" is not required nor mentioned in the 40 CFR. If the label under review is for a product which is a fumigant, refer to PR Notice 84-5 (Reference: PR-84-05) or relevant Registration Standards for the "Note to Physician." For all other products, we are currently requiring a "Note to Physician" as specified in the proposed rule for the following types of products:

- All products that are classified as toxicity category I.
- Any product which is corrosive or classified as toxicity category I for eye or skin.
- Products that are in acute oral toxicity category III, and contain > 10% petroleum distillate.
- Any product that produces physiological effects requiring specific antidotal or medical treatment such as: Cholinesterase Inhibitors (e.g., carbamates and phosphorothioates, and organophosphates); Metabolic Stimulants (e.g., dichlorophenols); Anticoagulants (e.g., warfarin).

- B. Contents of Note: The proposed rule does not provide specific notes to physicians except for corrosive and toxicity category I and II eye and skin irritants. The proposed rule does provide the following guidance concerning the content of notes to physicians. Check the label under review to make certain that it addresses the following information:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions; medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide
- specialized medical advice.

- C. Specific Note for Corrosive or Toxicity Category I Eye or Skin Irritants:

Use the following Note to Physician:

"Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

- D. Required Location: The "Note to Physician" should be located in close proximity to the "First Aid Statement" but should be clearly distinguished from it. In other words, it should not be mixed in with the "First Aid Statement" but should appear below the last first aid statement.

## 8. LABELING STATEMENTS FOR SPECIAL SITUATIONS

- A. Chemigation statement (PR Notice 93-7, Supplement 3, page 39)
- B. Soil incorporation/injection/seed treatment (PR Notice 93-7, Supplement 3, page 39)
- C. Engineering control statements (PR Notice 93-7, Supplement 3, page 50)
- D. ULV and LV uses (PR Notice 93-7, Supplement 3, page 40)

### Optional Labeling and Deviations

EPA will consider precautionary statements that deviate from the requirements of this chapter, provided they meet the conditions as described below:

1. USE DILUTIONS: Additional precautionary wording and first aid statements on the label are allowed on concentrated products that correspond with a use dilution of the product that is consistent with the product's directions for use. EPA policy allows such labeling provided data are submitted to support



such statements. The policy provided guidelines for the submission and review of such data and for the content and placement of associated labeling (Reference: LP96-03).

- A. Data Requirements: All data and draft labeling for use dilution precautionary wording and first aid statements should be sent to the appropriate product manager with a request for pesticide amendment.

Use dilution precautionary wording or first aid statements triggered by systemic toxicity (acute oral, dermal or inhalation toxicity) can be supported by calculations. Most systemic toxicity categories span an order of magnitude (10-fold). Therefore, in most cases, if dilutions are an order of magnitude or more, except for category I, they will bump up at least one toxicity category. For example, if the end product toxicity category is II and it will be diluted 10-fold, the diluted product will be at toxicity category III; if it is diluted 100-fold, it will be at toxicity category IV.

Use dilution precautionary wording or first aid statements triggered by skin or eye irritation or dermal sensitization must be supported by new or cited studies. If another registered dilute product (such as a ready to use formulation) has acceptable data and is found similar to the concentrated product after it has been diluted, that data may be used to support revised labeling.

- B. Labeling Requirements: It is important to remember that it is not our intent to allow dual sets of precautionary statements and/or first aid statements on the label. Rather, we will allow certain "additional" statements that are applicable to the most concentrated use dilution only. These additional statements (triggered by the toxicity category of the use dilution) should be placed directly after the required statements for the concentrate. Following are some examples (in parentheses) of how use dilution labeling should appear on product labeling: (actual use dilution statements will depend on data submitted).

Precautionary Statements:

"Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles or face shield. Wash thoroughly with soap and water after handling. Remove contaminated clothing before reuse. (After product is diluted in accordance with the directions for use, goggles or face shield are not required").

First Aid:

"If on skin: Wash with plenty of soap and water. Get medical attention. (If product, diluted in accordance with the directions for use, gets on skin, medical attention is not required.)

2. TOXICITY CATEGORY IV PRECAUTIONARY LABELING: If the product is all toxicity category IV (non-sensitizer), precautionary labeling statements are normally not required. However, if a registrant desires to place precautionary labeling on such a product, they may do so. To promote labeling consistency it is recommended that the registrant use precautionary statements triggered by toxicity category III. Registrants may propose alternate labeling, which should be reviewed by precautionary labeling reviewers.
3. ME-TOO DEVIATIONS: If a me-too product is citing a product that has optional precautionary statements on the label, such as 1. and/or 2. above, those statements are not required on the me-too if the acute results are available. If you have any questions about the availability of the acute studies, check with the precautionary labeling reviewers.

4. OTHER DEVIATIONS: Registrants may submit WPS and non-WPS precautionary labeling that differ from the requirements in this chapter. Such requests must be supported by data (or substantive justification) should be routed to precautionary labeling reviewers or the Chemistry and Exposure Branches (CB-I or II) (for PPE). For example, the statement "Do not remove contact lenses, if worn. Get immediate medical attention." cannot be approved by the Agency without supporting data or rationale.